

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Yukio SATO et al. **Confirmation No.: 6527**  
Serial No : 10/553,948 (National Stage of PCT/JP2004/005935)  
I.A. Filed : April 23, 2004  
For : METHYLATED CpG POLYNUCLEOTIDE

**INFORMATION DISCLOSURE STATEMENT**

Commissioner of Patents  
U.S. Patent and Trademark Office  
Customer Service Window, Mail Stop Amendment  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir:

Pursuant to 37 C.F.R. § 1.56 and 37 C.F.R. §§ 1.97-1.98,  
Applicants hereby direct the Examiner's attention to the following documents  
cited in the International Search Report for International Application  
PCT/JP2004/005935 of which the above-referenced is a National Stage:

- (1) KALNIK et al., "O<sup>6</sup>-Ethylguanine Carcinogenic Lesions in DNA: An  
NMR Study of O<sup>6</sup>etG•C Pairing in Dodecanucleotide Duplexes",  
Biochemistry, vol. 28 (1989), pp. 6182-6192;
- (2) KAWAI et al., "Intrastrand 2'β Hydrogen Abstraction of 5'-Adjacent  
Deoxyguanosine by Deoxyuridin-5-yl in Z-form DNA", Tetrahedron  
Letters, vol. 40 (1999), pp. 2589-2592;
- (3) LEE et al., "DNA Microstructural Requirements for Neocarzinostatin  
Chromophore-induced Direct Strand Cleavage", Nucleic Acids  
Research, vol. 17, no. 14 (1989), pp. 5809-5825;

- (4) ZHAO et al., "Site of Chemical Modifications in CpG Containing Phosphorothioate Oligodeoxynucleotide Modulates Its Immunostimulatory Activity", Bioorganic & Medicinal Chemistry Letters, vol. 9 (1999), pp. 3453-3458;
- (5) WO 03/27313 A2, April 3, 2003;
- (6) U.S. Patent Application Publication No. 2004/0248834 A1 (KLINMAN et al.), December 9, 2004; Applicants note that this document is a family member of document (5);
- (7) U.S. Patent Application Publication No. 2006/0074039 A1 (KLINMAN et al.), April 6, 2006; Applicants note that this document is a family member of documents (5) and (6);
- (8) JP 2003-510290 A, March 18, 2003;
- (9) WO 01/22990 A2, April 5, 2001; Applicants note that this document is a family member of document (8);
- (10) U.S. Patent No. 6,949,520 B1 (Hartmann et al.), September 27, 2005; Applicants note that this document is a family member of documents (8) and (9);
- (11) U.S. Patent Application Publication No. 2005/0169888 A1 (Hartmann et al.), August 4, 2005; Applicants note that this document is a family member of documents (8)-(10).

Applicants further direct the Examiner's attention to the following documents cited in the present application, beginning at page 1, second full paragraph:

- (12) SATO et al., "Immunostimulatory DNA Sequences Necessary for Effective Intradermal Gene Immunization", Science, vol. 273 (1996), pp. 352-354;
- (13) KRIEG et al. "CpG Motifs in Bacterial DNA Trigger Direct B-cell Activation", Nature, vol. 374 (1995), pp. 546-549;
- (14) MIYATA et al., "Unmethylated Oligo-DNA Containing CpG Motifs Aggravates Collagen-Induced Arthritis in Mice", Arthritis & Rheumatism, vol. 43, no. 11 (2000), pp. 2578-2582;
- (15) LEADBETTER et al., "Chromatin-IgG Complexes Activate B-cells by Dual Engagement of IgM and Toll-like Receptors", Nature, vol. 416 (2002), pp.603-607;
- (16) JP 2002-521489 A, July 16, 2002;
- (17) WO 00/06588 A1, February 10, 2000; Applicants note that this document is an English language family member of document (16).

Copies of the above-listed documents (with the exception of the U.S. patent and the U.S. patent applications), the International Search Report for International Application PCT/JP2004/005935 and the International Preliminary Report on Patentability thereof are enclosed together with a completed copy of the PTO-1449 Form listing these documents. Accordingly, the Examiner is requested to consider these documents and to indicate such consideration by


returning a signed and initialed copy of the PTO-1449 Form with the next official communication.

Further to 37 C.F.R. §1.98 (a)(2)(ii), copies of the U.S. patent and the U.S. patent applications are not enclosed herewith. However, if any copies are needed, the Examiner is respectfully requested to contact the undersigned.

Applicants note that an Office Action on the merits has not yet issued in the instant application, and thus, no fee is necessary to ensure consideration of this statement. However, if an Office Action has issued and is crossing in the mail with this statement, the Patent and Trademark Office is hereby authorized to charge Deposit Account No. 19-0089 any fee necessary to ensure consideration of the submitted materials.

If there should be any questions, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,  
Yukio SATO et al.

  
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FORM PTO-1449

U.S. Department of Commerce  
Patent and Trademark OfficeAtty. Docket No.  
P28700Application No.  
10/553,948

**INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT**  
(Use several sheets if necessary)

Applicant  
Yukio SATO et al.Filing Date  
I.A. Filed April 23, 2004Group  
Not Yet Assigned

**U.S. PATENT DOCUMENTS**

| EXAMINER<br>INITIAL |        | DOCUMENT NUMBER | DATE     | NAME            | CLASS | SUBCLASS | FILING DATE<br>IF APPROPRIATE |
|---------------------|--------|-----------------|----------|-----------------|-------|----------|-------------------------------|
|                     | 2004 / | 0 2 4 8 8 3 4   | 12/09/04 | KLINMAN et al.  |       |          |                               |
|                     | 2006 / | 0 0 7 4 0 3 9   | 04/06/06 | KLINMAN et al.  |       |          |                               |
|                     |        | 6 9 4 9 5 2 0   | 09/27/05 | HARTMANN et al. |       |          |                               |
|                     | 2005 / | 0 1 6 9 8 8 8   | 08/04/05 | HARTMANN et al. |       |          |                               |
|                     |        |                 |          |                 |       |          |                               |
|                     |        |                 |          |                 |       |          |                               |
|                     |        |                 |          |                 |       |          |                               |

**FOREIGN PATENT DOCUMENTS**

|  |         | DOCUMENT NUMBER | DATE     | COUNTRY  | CLASS | SUBCLASS | TRANSLATION<br>YES NO |
|--|---------|-----------------|----------|----------|-------|----------|-----------------------|
|  | 0 3     | / 0 2 7 3 1 3   | 04/03/03 | W.I.P.O. |       |          |                       |
|  | 2 0 0 3 | - 5 1 0 2 9 0   | 03/18/03 | JAPAN    |       |          |                       |
|  | 0       | 1 / 2 2 9 9 0   | 04/05/01 | W.I.P.O. |       |          |                       |
|  | 2 0 0 2 | - 5 2 1 4 8 9   | 07/16/02 | JAPAN    |       |          |                       |
|  | 0       | 0 / 0 6 5 8 8   | 02/10/00 | W.I.P.O. |       |          |                       |

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

|  |   |   |
|--|---|---|
|  | 1 | KALNIK et al., "O <sup>6</sup> -Ethylguanine Carcinogenic Lesions in DNA: An NMR Study of O <sup>6</sup> etG-C Pairing in Dodecanucleotide Duplexes", Biochemistry, vol. 28 (1989), pp. 6182-6192.                      |
|  | 2 | KAWAI et al., "Intrastrand 2'β Hydrogen Abstraction of 5'-Adjacent Deoxyguanosine by Deoxyuridin-5-yl in Z-form DNA", Tetrahedron Letters, vol. 40 (1999), pp. 2589-2592.   |
|  | 3 | LEE et al., "DNA Microstructural Requirements for Neocarzinostatin Chromophore-induced Direct Strand Cleavage", Nucleic Acids Research, vol. 17, no. 14 (1989), pp. 5809-5825.  |
|  | 4 | ZHAO et al., "Site of Chemical Modifications in CpG Containing Phosphorothioate Oligodeoxynucleotide Modulates Its Immunostimulatory Activity", Bioorganic & Medicinal Chemistry Letters, vol. 9 (1999), pp. 3453-3458. |
|  | 5 | SATO et al., "Immunostimulatory DNA Sequences Necessary for Effective Intradermal Gene Immunization", Science, vol. 273 (1996), pp. 352-354.  |
|  | 6 | KRIEG et al. "CpG Motifs in Bacterial DNA Trigger Direct B-cell Activation", Nature, vol. 374 (1995), pp. 546-549.  |
|  | 7 | MIYATA et al., "Unmethylated Oligo-DNA Containing CpG Motifs Aggravates Collagen-Induced Arthritis in Mice", Arthritis & Rheumatism, vol. 43, no. 11 (2000), pp. 2578-2582.   |
|  | 8 | LEADBETTER et al., "Chromatin-IgG Complexes Activate B-cells by Dual Engagement of IgM and Toll-like Receptors", Nature, vol. 416 (2002), pp.603-607.   |
|  |   |   |
|  |   |   |

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.